

4-1-2002

Defendant Dolly's Motion for Summary Judgment: Memorandum of Points and Authorities in Support Thereof

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Recommended Citation

Joe Andrieu, Lir Burke, Mimi H. Chiang Ph.D. & Elizabeth Hong, *Defendant Dolly's Motion for Summary Judgment: Memorandum of Points and Authorities in Support Thereof*, 35 Loy. L.A. L. Rev. 999 (2002).
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UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF CALIFORNIA

| | | |
|-------------------------|---|-------------------------------|
| NUGENERA, INC., a |) | CASE NO. MHP-01-9999 |
| California Corporation, |) | |
| |) | DEFENDANT DOLLY'S |
| Plaintiff, |) | MOTION FOR SUMMARY |
| |) | JUDGMENT: MEMORANDUM |
| vs. |) | OF POINTS AND |
| |) | AUTHORITIES IN SUPPORT |
| SALVADOR DOLLY and |) | THEREOF |
| DOES I-X, |) | |
| |) | Date: Nov. 9, 2001 |
| Defendants. |) | Time: 2:30 pm |
| _____ |) | Courtroom: Ramo Auditorium |

Defendant, SALVADOR DOLLY, by and through his counsel of record, respectfully submits this Memorandum of Points and Authorities in support of his Motion for Summary Judgment under Rule 56, Federal Rules of Civil Procedure. An Expert Witness

Statement of Defendant Dolly's expert, Richard A. Myers, Ph.D., is filed separately.

TABLE OF CONTENTS

I. INTRODUCTION 1006

II. QUESTIONS PRESENTED 1007

III. STATEMENT OF FACTS 1008

IV. ARGUMENT..... 1010

A. *Claim 1 and Claim 2 Are Invalid Because They Fail to Meet Statutory Standards for Patentability*..... 1010

1. Claim 1 and Claim 2 lack utility as required by 35 U.S.C. § 101 of the Patent Act of 1952 1010

a. *the DNA sequences of Claim 1 and Claim 2 have no well-established use* 1011

b. *neither Claim 1 nor Claim 2 demonstrates specific, substantial, and credible utility* 1013

i. element one: there is no specific utility for Claim 1 and Claim 2..... 1014

ii. element two: Claim 1 and Claim 2 have no substantial utility..... 1014

iii. element three: Claim 1 has no credible utility..... 1016

2. Claim 1 and Claim 2 lack enablement under 35 U.S.C. § 112, first paragraph, because they have no utility..... 1017

3. Claim 1 and Claim 2 are statutorily barred under 35 U.S.C. § 102(b) based on the prior art..... 1018

4. Claim 1 and Claim 2 are invalid for fundamental reasons of public policy—to grant exclusive rights over an individual’s genetic material to the extent of negating the individual’s own use of the genetic material is an unacceptable negation of the right to bodily autonomy 1018

a. *accepted practice in the health and research industry includes application of the highest standards of informed consent* 1018

b. *the right to bodily autonomy necessarily includes genetic material* 1020

c. *allowance and enforcement of intellectual property rights against the individual whose DNA provided the natural source of invention*

| | | |
|----|---|------|
| | <i>is unethical</i> | 1020 |
| d. | <i>patenting of an individual's genetic material without prior express consent from that individual is an invasion of one's genetic privacy</i> | 1021 |
| B. | <i>Defendant Dolly Alone Has the Constitutional and Common Law Right to the Use or Sale of His Own Genetic Material</i> | 1022 |
| 1. | Dolly has the sole property interest in his blood within his body | 1023 |
| 2. | Dolly's privacy rights are violated by enforcement of the '271 patent because enforcement would deny Defendant Dolly his fundamental right to disconnect his body from the public domain..... | 1026 |
| a. | <i>Dolly has a right to disconnect his body from invasive apparatuses that keep him alive</i> | 1027 |
| b. | <i>Dolly has a right to avoid genetic procreation</i> | 1027 |
| V. | CONCLUSION | 1030 |

TABLE OF AUTHORITIES

| Cases: | Page |
|--|------------------|
| <i>Bd. of Regents v. Roth</i> , 408 U.S. 564 (1972)..... | 1021 |
| <i>Brenner v. Manson</i> , 383 U.S. 519 (1966)..... | 1009, 1012, 1014 |
| <i>Brotherton v. Cleveland</i> , 923 F.2d 477 (6th Cir. 1991)..... | 1021 |
| <i>Bruning v. Hirose</i> , 161 F.3d 681 (Fed. Cir. 1998) | 1016 |
| <i>Cruzan v. Dir., Mo. Dep't of Health</i> , 497 U.S. 261 (1990)..... | 1022, 1026 |
| <i>Davis v. Davis</i> , 842 S.W.2d 588 (Tenn. 1992)..... | 1023, 1027, 1028 |
| <i>Eisenstadt v. Baird</i> , 405 U.S. 438 (1972)..... | 1022, 1026, 1027 |
| <i>Green v. Comm'r</i> , 74 T.C. 1229 (1980) | 1022 |
| <i>Griswold v. Connecticut</i> , 381 U.S. 479 (1965) | 1021 |
| <i>Hecht v. Superior Court</i> , 16 Cal. App. 4th 836, 20 Cal. Rptr. 2d 275 (Ct. App. 1993)..... | 1023, 1027 |
| <i>Hybritech Inc. v. Monoclonal Antibodies, Inc.</i> , 802 F.2d 1367 (Fed. Cir. 1986) | 1009 |
| <i>In re Brana</i> , 51 F.3d 1560 (Fed. Cir. 1995)..... | 1016 |
| <i>In re Citron</i> , 325 F.2d 248 (C.C.P.A. 1963)..... | 1010 |
| <i>In re Deuel</i> , 51 F.3d 1552 (Fed. Cir. 1995) | 1019 |
| <i>In re Isaacs</i> , 347 F.2d 887 (C.C.P.A. 1965)..... | 1010, 1014 |
| <i>In re Joly</i> , 376 F.2d 906 (C.C.P.A. 1967)..... | 1014 |
| <i>In re Kirk</i> , 376 F.2d 936 (C.C.P.A. 1967) | 1014, 1016 |
| <i>Moore v. Regents of the Univ. of Cal.</i> , 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990)..... | 1023, 1024, 1025 |
| <i>Nelson v. Bowler</i> , 626 F.2d 853 (C.C.P.A. 1980) | 1009, 1012 |
| <i>Planned Parenthood v. Casey</i> , 505 U.S. 833 (1992)..... | 1022, 1025 |
| <i>Raytheon Co. v. Roper Corp.</i> , 724 F.2d 951 (Fed. Cir. 1983)..... | 1016 |
| <i>Reno v. Flores</i> , 507 U.S. 292 (1993)..... | 1028 |
| <i>Skinner v. Oklahoma</i> , 316 U.S. 535 (1942)..... | 1022 |
| <i>Troxel v. Granville</i> , 530 U.S. 57 (2000)..... | 1027 |
| <i>Vacco v. Quill</i> , 521 U.S. 793 (1997) | 1026 |
| <i>Washington v. Glucksberg</i> , 521 U.S. 702 (1997) | 1026, 1028 |
| <i>Winston v. Lee</i> , 470 U.S. 753 (1985)..... | 1022 |
| <i>Zablocki v. Redhail</i> , 434 U.S. 374 (1978) | 1022 |

Statutes:

35 U.S.C. § 101 (1994)..... 1006, 1009, 1010, 1011, 1012, 1013, 1016
 35 U.S.C. § 102(b) (1994) 1017
 35 U.S.C. § 112 (1994)..... 1016
 Uniform Anatomical Gift Act, 8 U.L.A. 19 (1993)..... 1023

Court Documents:

Expert Test. Richard M. Myers, Ph.D.
 1000, 1010, 1011, 1015, 1016, 1018, 1019, 1020
 Pl.’s Compl. 1007, 1008, 1011

Other Authorities:

BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* (1983)..... 1012
Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Prop. of the House Comm. on the Judiciary, 106th Cong. (2000)
..... 1011, 1012, 1014, 1018
 The Genetic Privacy Act of 1995 (Feb. 28, 1995), *available at* <http://www.ornl.gov/hgmis/resource/privacy/privacy1.html> ... 1020
 John B. Hogenesch et al., *A Comparison of the Celera and Ensembl Predicted Gene Sets Reveals Little Overlap in Novel Genes*, 106 CELL 413 (2001). 1014
Institutional Review Board Guidebook, at http://ohrp.osophs.dhhs.gov/irb/irb_chapter3.htm (last visited Feb. 26, 2002)..... 1018
 MANUAL OF PATENT EXAMINING PROCEDURE (8th ed., 2001) 1012
Proprietary Rights and the Human Genome Project: A Legal and Economic Perspective, 8 DIG. 45 (2000)..... 1024
 Patricia (Winnie) Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 37 JURIMETRICS J. 1 (1996)..... 1021
 U.S. CONST. amend. V 1021
 U.S. Patent and Trademark Office, *Revised Interim Utility Guidelines Training Materials, at* <http://www.uspto.gov/web/patents/guides.htm> (last visited Feb. 26, 2002)
 1009, 1010, 1011, 1012

U.S. Patent No. 6,025,154 (issued Feb. 15, 2000).....1013
Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5,
2001).....1009, 1010, 1012, 1013, 1015

I. INTRODUCTION

Possession of one's own body is an inherent and fundamental human right that cannot be abrogated simply because legislation has not kept pace with advances in biotechnology. Yet, this is precisely what Plaintiff is attempting to successfully assert with its patent infringement suit against Defendant Salvador Dolly.

Recent developments in biotechnology have created a wellspring of intellectual property based on the building blocks of life; Deoxyribo Nucleic Acid (DNA). One's genome is a necessary and unique element of every human being as it contains the template of instructions for each individual. Not only does one's DNA contain vital genetic life instructing information, it also encodes for the uniquely personal and inherited set of instructions it comprises. Therefore, an individual's genetic composition, both as a chemical composition and as the source of personal information for which it encodes, is as much one's individual property as any other part of one's body. The United States Patent and Trademark Office (PTO) has correctly classified DNA compositions as patentable inventions, but only if statutory requirements for patentability are met. One must keep in mind that while DNA compositions are patentable, they differ uniquely from other patentable compositions in that their value to the source individual (i.e., as genetically private material) cannot be separated from their utility to society as a whole.

In keeping up with growing concern over whether genes should be patentable, if maintaining their patentability outweighs their potential invasion of privacy, the PTO has promulgated a new set of utility guidelines that follow court precedent and set a higher and more clarified standard of utility required for patenting gene inventions. Unfortunately, Plaintiff's patent has slipped through the loopholes of the patent process. Plaintiff has, without Dolly's consent, patented his entire genome. Plaintiff's patent also seeks to assert proprietary rights over ten specific genes belonging to Dolly, despite a gross failure to meet basic tests of patentability, utility, enablement, and anticipation. In this case, Plaintiff attempts to further extend its ill-gotten monopoly and exclude Dolly's sale of his own whole blood.

Courts have repeatedly affirmed an individual's right to control his or her own property. Every individual has proprietary rights and

original ownership over their own body tissue. This right can only be relinquished with the original owner's consent. If Plaintiff's patent claims are valid, public policy prohibits its enforcement. Any inventive contribution made by Plaintiff was made possible only as a result of its misappropriation of Dolly's tissue and by subsequent violation of Dolly's genetic privacy. Sound public policy mandates invalidation of Plaintiff's U.S. Patent No. F6,635,271 ('271 patent) patent claims and a return of the intellectual property to its rightful owner. Therefore, Defendant Dolly's Motion for Summary Judgment should be granted.

II. QUESTIONS PRESENTED

1. Is a claim to a single individual's entire genome valid in light of 35 U.S.C. § 101?
2. Can a patent for an isolated genetic composition (DNA) provide the basis for a cause of action prohibiting use of the DNA and the unique information it contains by the individual who carries that DNA?
3. Do the traditional principles underlying a patent's purpose and proprietary rights it provides permit a finding of patent validity and the enforceability over an individual whose own tissue was the foundation for the patented invention?
4. Can specific DNA sequences from a single individual be credibly identified as *the* genes conferring Human Immunodeficiency Virus (HIV) resistance (or any phenotype)—absent an epidemiological study of a statistically significant population?
5. Can a patent claim remain valid and enforceable if misappropriated tissue formed the basis for such a claim?
6. Is it good public policy to find a claim valid or to enforce an issued claim where the claimed subject matter encompasses an individual's own DNA and excludes that individual's right to use his own DNA?
7. Is it good public policy to allow the patenting of an individual's genetic material if doing so is an invasion of that individual's fundamental right to privacy?

III. STATEMENT OF FACTS

Plaintiff NuGenEra, Inc. (NuGenEra) is a commercial business entity whose principal place of business is Santa Clara, California. On August 5, 1999, patent application serial No. 9,432,341 was filed with the PTO by Acosta et al. and assigned to NuGenEra. Subsequently, the '271 patent was issued on May 28, 2000. The subject matter of the claimed invention encompasses Defendant Salvador Dolly's entire genome (Dolly Genome) as well as ten other specific gene combinations (P or P1-P10) from Dolly's genome. Plaintiff NuGenEra's Complaint alleges that Defendant Dolly engaged in the sale and offered to sell his own genome. Further, the Complaint alleges that this sale and the offer to sell his genome within the United States is an infringement of Claim 1 and Claim 2 of the '271 patent.

Dolly is a married individual who resides in California. Dolly and his wife had been trying for several years to conceive. After several unsuccessful attempts, Mr. and Mrs. Dolly decided to pursue other advanced treatments for infertility. As part of this endeavor, they decided to seek genetic testing prior to embarking on in vitro fertilization in order to rule out any possibility of passing on genetically based traits to their unborn child. Therefore, on July 31, 1998, Dolly provided three whole-blood samples to Advanced Genetic Testing Company (AGTC).

According to the agreement, the samples were only to be tested with currently available diagnostic methods for any known inheritable disease-associated genes. Mr. and Mrs. Dolly paid for the cost of sampling and genetic tests performed by AGTC because their standard health insurance policy did not pay for it. Prior to withdrawal of his blood samples, Dolly signed AGTC's consent form, allowing AGTC to carry out the genetic tests on his tissue samples. (*See Pl.'s Compl., App. A.*)¹

The consent form specifically stipulates that Dolly consented to the testing of "known genetically-based diseases" such as

1. The *Loyola of Los Angeles Law Review* will not be publishing the Complaint or Appendix A referenced in Defendant Dolly's Points and Authorities. Appendix A contains NuGenEra's Consent Form at issue in this case. To obtain a copy of the Complaint and Appendix A, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, at <http://techlaw.lls.edu/atc3/pleadings.html>.

“Tay-Sachs Disease, thalassemia, sickle cell disease, Familial Mediterranean Fever [a]nd Phenylketonuria (PKU).” (Pl.’s Compl., App. A.) Dolly was initially concerned about the use and testing of his tissue and DNA samples. But the following passage in the consent form assuaged his fears: “I understand that all information will be confidential and will not be disclosed by Advanced Genetic Testing staff, except to my personal physician as identified below.” (Pl.’s Compl., App. A.) The consent form further stipulated that the only information to be provided by AGTC would be “results of my [Dolly’s] genetic testing.” (Pl.’s Compl., App. A.) Due to the extremely specific and limited nature of this consent, Dolly signed the consent form and proceeded with the genetic tests. At no time then, nor after, was Dolly informed of, nor did he consent to, any other use of his tissue samples or additional testing of his tissue samples.

After Mr. and Mrs. Dolly successfully conceived and gave birth to their first child, Dolly was approached by various academic research institutions requesting samples of his tissue because Dolly was naturally resistant to HIV infection. On November 30, 2000, Dolly, as part of a limited partnership (Dolly Deal), sold a single whole-blood sample to Dr. William Morgan of the University of California. A few weeks later, on December 12, 2000, Dolly sold a second whole-blood sample to Dr. Paul Hu of California State University. As a longtime supporter of academic research, Dolly was hopeful that his contribution to the field of Acquired Immune Deficiency Syndrome (AIDS) research would mature into a valuable and useful therapeutic tool for those suffering from HIV. Additionally, Dolly was hopeful of securing a steady income flow for his new family. A few weeks later, Dolly and his partnership offered to sell a whole-blood sample to Dr. Antoinette Avazian, of Infants’ Hospital. Dr. Avazian is well known in the field of pediatric AIDS research and had suggested to Dolly on several occasions that he should consider making available his tissue samples for AIDS research, which Dolly did by donating blood to the Red Cross on numerous occasions.

Until Dolly was served with NuGenEra’s infringement suit, Dolly was unaware of the existence of the ‘271 patent. In fact, Dolly was under the belief that the tissue sample given to AGTC in 1998 had long been incinerated following its use for genetic testing. Dolly

was never informed that his own genetic material was being used by NuGenEra for purposes of obtaining exclusive patent rights on their behalf. Furthermore, Dolly was shocked to learn that the DNA sequence of his own entire genome had been published and made publicly available as a result of the patenting and publication of the '271 patent. Dolly is an individual who considers the privacy of his body, especially his genetic privacy, to be the most valuable of his basic rights.

IV. ARGUMENT

A. Claim 1 and Claim 2 Are Invalid Because They Fail to Meet Statutory Standards for Patentability

1. Claim 1 and Claim 2 lack utility as required by 35 U.S.C. § 101 of the Patent Act of 1952

Patent claims that fail to meet statutory utility requirements are invalid. Section 101 of the Patent Act of 1952 provides that “[w]hoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” may obtain a patent on the invention or discovery. 35 U.S.C. § 101 (1994) (emphasis added). This means that inventions lacking usefulness are not patentable. For example, the identification of a DNA sequence having no known function or no known target is deemed non-useful for patentable purposes. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986) (explaining that where patent specification failed to disclose a specific target disease for the claimed compounds, the claimed compounds lacked utility); *see also* U.S. Patent and Trademark Office, Revised Interim Utility Guidelines Training Materials, at <http://www.uspto.gov/web/patents/guides.htm> [hereinafter *Training Materials*].

The Supreme Court has defined the statutory term “useful” as requiring disclosure of at least one “specific” and “currently available” utility. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966). In other words, the claimed invention must contribute some “real-world value” so that one skilled in the art can use the discovery in a way that provides “practical utility” to the public. *See Nelson v. Bowler*, 626 F.2d 853, 855-56 (C.C.P.A. 1980).

The PTO's new Utility Examination Guidelines (Utility Guidelines) require that a claimed invention either have a "well-established utility" or assert a "specific, substantial, and credible utility." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001). The Utility Guidelines are consistent with established case law, and are based on both statutory directives and court precedent. *See id.* at 1096. A well-established utility is a use that is "well known," "immediately apparent" or implied by the specifications' disclosure alone, or taken with the knowledge of one skilled in the art. *See Training Materials, supra*, at 7. In order to maintain its patentability, a patent that fails to assert a well-established utility must then assert a "specific, substantial, and credible" utility. Utility Examination Guidelines, 66 Fed. Reg. at 1095. (emphasis added).

Claim 1 is directed at all of the nucleic acid sequences comprising Dolly's entire chromosomal DNA (i.e., Dolly's entire genome). Claim 2 is directed at ten gene sequences possibly involved in conferring HIV resistance. However, as shown below, Plaintiff's '271 patent fails to assert any utility that would be useful to either the public at large or to one of ordinary skill in the art. In fact, based upon a detailed reading of the '271 patent, any alleged utility that is asserted is "incredible in the light of the knowledge of the art, or factually misleading," thereby rendering the '271 patent invalid under 35 U.S.C. § 101. *In re Isaacs*, 347 F.2d 887, 890 (C.C.P.A. 1965) (quoting *In re Citron*, 325 F.2d 248, 253 (C.C.P.A. 1963)).

a. the DNA sequences of Claim 1 and Claim 2 have no well-established use

Neither Claim 1 nor Claim 2 has an established, much less a "well-established," utility. Claim 1 provides the nucleic acid sequences comprising all of Defendant Dolly's entire genome. There is no well-established use in owning someone else's entire genome. (*See* Expert Test. Richard M. Myers, Ph.D. at 5.)² Besides

2. The *Loyola of Los Angeles Law Review* will not be publishing the Expert Testimony of Richard Myers referenced in Defendant Dolly's Points and Authorities. To obtain a copy of Richard Myers' Expert Testimony, see *The Program for Law and Technology at California Institute of Technology & Loyola Law School* Web site, at <http://techlaw.lls.edu/atc3/pleadings.html>.

conferring in Plaintiff exclusionary rights to Dolly's genome (i.e., preventing Dolly from isolating and using his own DNA), the only other "use" in owning Dolly's entire genome would be to clone another individual who is genetically identical to Dolly. This also is not a credible utility. (See Expert Test. Richard M. Myers, Ph.D. at 5.) Neither of those uses are (nor should be) well-established.

The '271 patent also fails to assert any well-established utility for Claim 2. Claim 2 of the '271 patent provides: "A combination of isolated nucleic acid sequences comprising SEQ ID NOs: P1-P10," where P1-P10 are a combination of genes which either alone or in combination "increases" a cell or animal's resistance to HIV. (Pl.'s Compl., App. B.)³

Plaintiff's '271 patent "does not disclose or provide any evidence that points to an activity" for the claimed DNA sequences, as required by the Utility Guidelines. *Training Materials, supra*, example 9. There is also "no art of record that discloses or provides any evidence that points to an activity for the target" DNA. *Id.* Instead, the '271 patent merely provides DNA sequences derived from an individual who is naturally resistant to HIV infection. In order to meet the § 101 requirement, a patent must identify, "unless it's already well established, a specific, substantial, and credible utility for" the invention. *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Prop. of the House Comm. on the Judiciary*, 106th Cong. 6 (2000) [hereinafter *Hearing*] (statement of Todd Dickinson, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, Department of Commerce). The '271 patent is silent as to the target sequences and their function. Throughout the patent's entire three-page specification, there is no disclosure of where the gene sequences lie, no disclosure of what the genes are useful for, and certainly no assertion of any real-world use. In the absence of any disclosed or known use, Claim 2 cannot have any well-established use. In a best case scenario, the DNA sequences of Claim 2 could only be used by one skilled in the art for their further research. Claim 1 and Claim 2 are not patentable because of their failure to assert any well-established use. In order

3. Appendix B of the Complaint refers to United States Patent Number F6,635,271, the patent at issue in this case, which is published at 971.

for Claim 1 and Claim 2 to satisfy the utility requirement, the '271 patent must, therefore, assert a specific, substantial, and credible use. *See id.*

b. neither Claim 1 nor Claim 2 demonstrates specific, substantial, and credible utility

Claim 1 and Claim 2 are also invalid because they have no specific, substantial, and credible utility as required by 35 U.S.C. § 101. *See Brenner*, 383 U.S. at 534-35; *Nelson*, 626 F.2d at 856; Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). Specifically, the Utility Guidelines set forth three elements that must be met for patentable utility: 1) the claimed invention must have a utility specific to the subject matter claimed; 2) the utility must be substantial; and 3) the utility must be credible. *See Utility Examination Guidelines*, 66 Fed. Reg. at 1098. These criteria set the utility standard for gene patents at "an appropriate level to ensure incentives for [both] research and the efficient dissemination of valuable data." *Hearing, supra*, at 6 (statement of Todd Dickinson). Claim 1 and Claim 2 not only lack all three criteria, but they also fail to meet any single one of the above three requisite assertions.

A "specific" utility is one that is particular to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. *See Utility Examination Guidelines*, 66 Fed. Reg. at 1098. A "substantial" utility imparts a real-world use (i.e., of immediate, not theoretical use). *See Training Materials, supra*, at 7. A "credible utility" is one that a person of ordinary skill in the art would believe. *See Utility Examination Guidelines*, 66 Fed. Reg. at 1098. In other words, unless one of ordinary skill in the art would have rational basis to doubt the truth. *See MANUAL OF PATENT EXAMINING PROCEDURE* § 2107 (8th ed., 2001).

Chemical compositions as compounds are patentable subject matter. *See* 35 U.S.C. § 101. Isolated DNA sequences are chemical compositions, and like other chemicals, have specific molecular structures that impart specific properties. Even slight variations in the chemical structure (i.e., sequence) of DNA can result in large changes in activity. *See BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL* 473-75 (1983). DNA sequences that have an established function (i.e., useful as probes for known disease-related

genes, or share homology with sequences encoding proteins of known function) are “useful” and, therefore, patentable. *See* Utility Examination Guidelines, 66 Fed. Reg. at 1095-97. Some DNA compositions are useful for patentable purposes because they have a scientifically established function (e.g., DNA sequence encoding the HIV co-receptor CCR5 gene). *See* U.S. Patent No. 6,025,154 (issued Feb. 15, 2000). However, a DNA sequence having a purely speculative function can still be useful for patentable purposes if the sequence shares structural similarity to other DNA sequences encoding proteins of well-known functions. Claim 1 and Claim 2 of the ‘271 patent fall into neither of these categories. Patentable utility requires an assertion of at least one “specific, substantial, and credible utility.” As shown below, the ‘271 patent does not assert a specific, substantial, and credible utility for the claimed DNA sequences. As such, Claim 1 and Claim 2 are invalid for lack of utility.

i. element one: there is no specific utility for Claim 1 and Claim 2

A utility is “specific” when it is particular to the subject matter claimed. *See* Utility Examination Guidelines, 66 Fed. Reg. at 1098. For example, raw DNA sequence data is not patentable because there is no specific utility associated with it. *See id.* Claim 1 is raw DNA sequence data. Therefore, Claim 1 lacks a specific utility.

Claim 2 lacks a patentable specific utility because the claimed sequences have no known target gene. There is no asserted function, characterization, or description of the nature of the genes allegedly conferring HIV resistance. All that is known is that the P sequences are involved in increased HIV resistance. Plaintiff never isolated, identified, characterized, or even described the nature of those sub-cellular factors involved in increasing HIV resistance. Nor are these actions well-known in the art. Absent a disclosure of what genes or proteins to which the P sequences are associated, Claim 2 is invalid for lack of a specific utility.

ii. element two: Claim 1 and Claim 2 have no substantial utility

A substantial utility defines a “real world” or “practical” context of use. The Supreme Court has pointed out that “[u]nless and until a process is refined and developed to this point—where specific

benefit exists in *currently available form*—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” *Brenner*, 383 U.S. at 534-35 (emphasis added). An invention’s usefulness as a research tool is insufficient to meet statutory standards of patentability. Therefore, basic research using a claimed DNA sequence for studying the properties of the DNA itself is not “a substantial utility.” *See Hearing, supra*, at 6 (statement of Todd Dickinson).

Plaintiff has allegedly identified ten genes possibly capable of conferring HIV resistance. Claim 2 is directed at those ten sequences. Because DNA sequences generally encode for proteins, it is likely that P directs synthesis of protein products. However, the ‘271 patent does not disclose any information regarding the nature of the claimed sequences or protein products. Of course, it is also possible that the P sequences are enhancer sequences involved in regulating expression of other genes. Nevertheless, Plaintiff has neither identified nor suggested possible biological roles of the protein products. Absent this information, the claimed P sequence does not possess any immediate practical utility that is “substantial.”

Although the Claim 1 sequences can be used for further research studies into HIV, it still fails to satisfy the utility requirement. In order to be patentable, a claimed invention must be useful for more than further research on itself. *See In re Kirk*, 376 F.2d 936 (C.C.P.A. 1967). Even if Plaintiff can assert that the DNA sequences of Claim 2 are useful for identifying an HIV associated gene, an HIV preventative gene, or even for human gene therapy, all of these are highly speculative uses and are therefore not credible. Patents that assert speculative uses fail to meet statutory utility requirements. *See In re Isaacs*, 347 F.2d at 888-90. In order to satisfy the utility requirement, the patent specification must assert some utility for the final product of the “claimed intermediate.” *See In re Joly*, 376 F.2d 906 (C.C.P.A. 1967).

Turning now to Claim 1’s lack of substantial utility, Claim 1 encompasses Dolly’s entire genome. A human genome consists of thirty-thousand to one-hundred-thousand genes. *See John B. Hogenesch et al., A Comparison of the Celera and Ensembl Predicted Gene Sets Reveals Little Overlap in Novel Genes*, 106 CELL 413, 413-15 (2001). Plaintiff has identified ten genes believed to confer HIV resistance. This leaves over ninety-nine-thousand (or

ninety-nine percent) of Dolly's genes as completely uncharacterized, unpatentable raw sequence data. Therefore, the only real-world utility provided by Claim 1 is use of the ten P sequences that are contained within the claimed genome (i.e., subject matter encompassed by Claim 2). As is the case for Claim 2, Claim 1 is also invalid for lack of substantial utility.

iii. element three: Claim 1 has no credible utility

An asserted utility is "credible" unless the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). The '271 patent discloses that cells and animals carrying one or more of the genes of Claim 2 have increased resistance to HIV. No evidence, however, is provided to exclude the possibility that the observed HIV resistance is not due to an effect from some other background DNA sequence present in either Dolly himself, the test cell, or the test animal. Accepted standards in the field of genetics require a sufficient sampling of test DNA from separate sources of individuals all having a common phenotype, before a determination that a putative DNA sequence is actually associated with that disease or trait can be made. (*See* Expert Test. Richard M. Myers, Ph.D.)

Generally, identification of a disease-related gene requires epidemiological and linkage studies on hundreds of individuals. Here, Plaintiff has identified ten separate genes that allegedly confer HIV resistance. In order to assert a utility for these claimed sequences that is credible to one skilled in the art, Plaintiff must show they have the correct ten sequences. At a minimum, Plaintiff must show that "one or more" P gene combination confers HIV resistance. Simultaneously, Plaintiff must exclude the possibility that it is not any one or more of the other one hundred thousand genes also present in the test cell or animal (i.e., control background DNA) that is conferring HIV resistance. In order to do this, a minimum of 1.8 billion separate assays per control background DNA source must be tested for the ten sequences (where each sequence is separately, and then in all possible combinations, inserted into a normal cell or animal with resulting increased HIV resistance). This type of study is virtually impossible to conduct, physically and scientifically. The '271 patent discloses gene sequences identified

from a single individual. This is insufficient to show a believably acceptable causal link between any specific DNA sequence and Dolly's HIV resistant trait with respect to other individuals. Therefore, one skilled in the art fails to find a credible utility for the Claim 2 alleles. (See Expert Test. Richard M. Myers, Ph.D.) Because both Claim 1 and Claim 2 are invalid for lack of utility, Defendant Dolly requests dismissal of this case.

2. Claim 1 and Claim 2 lack enablement under 35 U.S.C. § 112, first paragraph, because they have no utility

Although the requirement that an invention have specific, substantial, and credible utility is found in 35 U.S.C. § 101, it is also implicit in 35 U.S.C. § 112, paragraph one. See *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995). Section 112, paragraph 1 of 35 U.S.C. reads:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (1994) (emphasis added). “[I]f a claimed invention does not have utility, the specification cannot enable one to use it.” *In re Brana*, 51 F.3d at 1564. Therefore, lack of enablement and absence of utility are closely related grounds of unpatentability. See *Raytheon Co. v. Roper Corp.*, 724 F.2d 951 (Fed. Cir. 1983). Whether a disclosure is enabling is a legal conclusion based on underlying factual inquiries and subject to de novo review. See, e.g., *Bruning v. Hirose*, 161 F.3d 681, 686 (Fed. Cir. 1998). Claim 1 and Claim 2 clearly fail to meet the utility requirement as set forth above. Claim 1 and Claim 2 are not supported by a well-established, or specific, substantial, and credible utility. Therefore, one skilled in the art would not know how to use the claimed invention. A patent disclosure that fails to teach one skilled in the art “how to make and use” the claimed invention, is invalid for lack of enablement. See *In re Kirk*, 376 F.2d at 942. Thus, Claim 1 and Claim 2 also are invalid because they fail to comply with the enablement requirements of 35 U.S.C. § 112, paragraph one.

3. Claim 1 and Claim 2 are statutorily barred under 35 U.S.C. § 102(b) based on the prior art

In addition to other grounds of invalidity, Claim 1 and Claim 2 are invalid due to prior art. Defendant Dolly has given blood samples numerous times since his birth. Indeed, the original source of tissue from which Plaintiff derived its claimed sequence information was a tissue sample Defendant Dolly gave to AGTC on July 28, 1998. This was over one year prior to the filing date of the '271 patent (August 5, 1999). Title 35 U.S.C. § 102(b) states that a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or *in public use* or on sale in this country, *more than one year prior* to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (1994) (emphasis added). Therefore, Claim 1 and Claim 2 are statutorily barred because of Defendant Dolly's own prior use and by the prior sampling of his tissue by AGTC. Claim 1 and Claim 2 are also invalid under 35 U.S.C. § 102(b). Accordingly, Defendant Dolly requests dismissal of this case.

4. Claim 1 and Claim 2 are invalid for fundamental reasons of public policy—to grant exclusive rights over an individual's genetic material to the extent of negating the individual's own use of the genetic material is an unacceptable negation of the right to bodily autonomy

a. accepted practice in the health and research industry includes application of the highest standards of informed consent

The patenting of another individual's genome without his consent is unconscionable. Indeed, it is a violation of all moral and ethical codes—a type of violation that transcends even current challenges and concerns regarding the patentability of DNA inventions and the consequences of granting such patents. Allowing intellectual property rights over an individual's genome without that individual's consent is an abandonment of the state's responsibility to create and maintain for its citizens a proper legal context for life, liberty, and the pursuit of happiness.

This is not the first time in our nation's history that legislation failed to keep pace with technology. However, given the bullet speed with which biotechnology has advanced and the technical, as

well as legal, complexity of the subject matter involved, it is understandable. As stated by California Representative, Howard L. Berman at the July 2000 House of Representatives Subcommittee Hearing on Gene Patents and Other Genomic Inventions, “[t]hese are very complex issues dealing in arcane areas of science and law” relating to “the legal and moral issues that are raised by patenting in new areas of technology.” *Hearing, supra*, at 3 (opening statement of the Hon. Howard L. Berman, member, House Subcommittee on Courts and Intellectual Property).

This is a case where legislative failure to keep pace with biotechnology has resulted in severe consequences. The issuance of the ‘271 patent has allowed the theft and improper commercialization of an innocent individual’s genetic material—the embodiment of nature’s instructions for making an individual a living being. Good public policy reflects the fundamental rule that every citizen has an inherent right to his personal property and genetic privacy. Although not yet statutorily mandated, most scientists, clinicians, and health practitioners adhere to this right through the mechanism of informed consent.

The accepted practice in the health and research industry (both commercial and academic) is application of the highest standard of informed consent. This standard of informed consent is applied for all tests and research that is conducted (or even anticipated to be conducted) using any part of an individual (both tangible and intangible). (*See* Expert Test. Richard M. Myers, Ph.D.); *see Institutional Review Board Guidebook*, at http://ohrp.osophs.dhhs.gov/irb/irb_chapter3.htm (last visited Feb. 26, 2002). Every federally funded laboratory conducting studies involving humans (and animals) must adhere to strict formal guidelines that IRB administers. Always included in these guidelines, and one of the clearest and most respected rules within the guidelines, is that of informed consent. *See Institutional Review Board Guidebook, supra*. Also reflected in this standard is the underlying policy of the medical and research community of maintaining a patient’s inherent and fundamental right to decide what to do with his own body.

Although a legal requirement for consent has been applied in other areas of the law, this is not the case here. There is no current statute available requiring that consent be given by an individual prior to the use of his or her tissue for subsequent patenting or

commercialization. Yet legislative responsiveness does not remove fundamental issues of right and wrong. Nor does it replace the ethical and moral imperatives that reflect our society's policy goals, or reassure our citizens of our court's ability to make the proper decision in the face of novel and unprecedented demands on our jurisprudence.

b. the right to bodily autonomy necessarily includes genetic material

An individual's genome is a unique and uniquely defining element of that individual. It is inviolably one's own property, as much as a heart, or brain, or blood is one's own property. One's genetic material is an especially important part of one's body because the information it encodes is inseparable from its chemical composition. See *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). In other words, taking, removing, or isolating a person's DNA necessarily includes giving access to the information contained in that DNA compound. It is the extent of information contained in this chemical composition that endows it with the potential power to greatly harm the very individual from which it is derived. For this reason, courts must uphold every individual's right to use, and control the use of, their own person. Here, the court must find the claims of '271 patent invalid for fundamental reasons of public policy. To hold otherwise would be to reward Plaintiff's unauthorized use of Defendant Dolly's DNA, as well as to annihilate Dolly's right to maintain bodily autonomy.

c. allowance and enforcement of intellectual property rights against the individual whose DNA provided the natural source of invention is unethical

What would happen if the courts allowed the wholesale appropriation and patenting of one's DNA without his or her consent? Imagine a world where every handshake, every use of a restroom, every haircut, and even every physical contact is a possible opportunity for some inventor to sample your DNA. Even worse, imagine a world where one's DNA might be stolen to develop biotechnological products in violation of that individual's deeply held personal and religious beliefs about the sanctity of human life and the inviolable role of God (or our parent's DNA) in shaping our children. Can we stand today and support a world where the

commercial interests of “genomic” thieves are not merely tolerated, but rewarded by our state with a legal monopoly to exploit their ill-gotten gains? We cannot. Even those scientists (arguably the ones with the most to lose if gene patents are not deemed allowable) do not condone the use of, or research on, a person’s genetic material without the explicit prior consent of that person. (See Expert Test. Richard M. Myers, Ph.D. ¶ 20.)

The scientific community (as a reflection of good public policy) concurs that any advance we may find in the realm of biotechnology cannot come at the sacrifice of an individual’s right to bodily autonomy and control over his or her genetic material. There is no reason to allow the use, research, or patenting of an individual’s genetic material without informed consent because to prohibit such activity would not in any way deter or reduce biotechnological advances. The majority of individuals when approached by scientists for use of their tissue in research are willing to provide their consent. (See Expert Test. Richard M. Myers, Ph.D.) Indeed, at last count, over eighty percent of those individuals contacted had signed consent forms permitting research use of their genetic material. (See Expert Test. Richard M. Myers, Ph.D.) Therefore, Plaintiff’s ‘271 patent of Defendant Dolly’s genetic material is invalid, if not for reasons of statutory lack of utility, then at least for fundamental reasons of public policy.

d. patenting of an individual’s genetic material without prior express consent from that individual is an invasion of one’s genetic privacy

What about other uses of stolen DNA? While this case draws our attention to the unpatentability of misappropriated genetic materials, we cannot ignore the larger ramifications of the decision to be made by this Court. Will this Court support the unregulated theft of Defendant Dolly’s DNA? Can we allow, thereby condone, Plaintiff’s unauthorized patenting of Defendant Dolly’s genome and resulting public access to what should be Defendant Dolly’s private genetic information? The published ‘271 patent disseminated Dolly’s personal genetic code for the world to see—his biological essence. One’s right to genetic privacy and its accompanying protection against genetic discrimination is stated in the proposed Genetic Privacy Act, which states:

[A]ny information about an identifiable individual that is derived from the presence, absence, alteration, or mutation of a gene or genes, or the presence or absence of a specific DNA marker or markers, and which has been obtained: (1) from an analysis of the individual's DNA; or (2) from an analysis of the DNA of a person to whom the individual is related.

Patricia (Winnie) Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 37 JURIMETRICS J. 1, 7 (1996) (describing the proposal by George Annas, et al.) (quoting The Genetic Privacy Act of 1995, § 3(m) (Feb. 28, 1995), available at <http://www.ornl.gov/hgmis/resource/privacy/privacy1.html>). An obvious extension of the legislative policy reflected in this Act is to find invalid those patents that violate one's right to genetic privacy. The '271 patent is one such patent. For fundamental reasons of public policy, the '271 patent should be ruled invalid because it violates Dolly's right to genetic privacy.

B. Defendant Dolly Alone Has the Constitutional and Common Law Right to the Use or Sale of His Own Genetic Material

The Fifth Amendment to the United States Constitution states: "No person shall be . . . deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation." U.S. CONST. amend. V. To define protected property interests, the Supreme Court generally looks to "existing rules or understandings that stem from an independent source," such as federal and state statutes and common law. *See Bd. of Regents v. Roth*, 408 U.S. 564, 577 (1972). As such, the legal definition of property is most often conceptualized as a bundle of rights: "rights to possess, to use, to exclude, to profit, and to dispose." *Brotherton v. Cleveland*, 923 F.2d 477, 481 (6th Cir. 1991).

In addition, the constitutional protection of due process "liberty" creates the right to privacy. *See Griswold v. Connecticut*, 381 U.S. 479, 484 (1965). Some of these privacy rights are deemed "fundamental" and thus afforded a heightened protection of "strict scrutiny;" these fundamental privacy rights include, inter alia, the rights to marry, use contraceptives, choose an abortion, resist compulsory sterilization, refuse medical treatment, maintain bodily

integrity, and create and maintain intimate relationships free from governmental interference. See *Planned Parenthood v. Casey*, 505 U.S. 833, 834, 846 (1992); *Cruzan v. Dir., Mo. Dept. of Health*, 497 U.S. 261, 269-70, 281 (1990); *Winston v. Lee*, 470 U.S. 753, 759, 767 (1985); *Zablocki v. Redhail*, 434 U.S. 374, 381-83 (1978); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942).

Here, the Government has violated Dolly's constitutional rights to both property and privacy by issuing patent protection to NuGenEra for Dolly's unique genome and gene combination. Granting NuGenEra the right to exclude others (including Dolly) from the *use* and *manufacture* of Dolly's isolated genome, gene combination, and an immortalized human cell line thereof, denies Dolly's liberty to profit from productive use of his body. In addition, this grant also denies Dolly's liberty to control procreation and maintain an intimate relationship free from governmental interference. Accordingly, the government's issuance of the '271 patent is unconstitutional, thus rendering the patent invalid.

1. Dolly has the sole property interest in his blood within his body

The property interest in one's removed blood was upheld in *Green v. Commissioner*, 74 T.C. 1229 (1980). In *Green*, the petitioner earned her living by selling her rare type AB-negative blood. In holding that petitioner's blood plasma was considered property, the court stated:

The rarity of petitioner's blood made the processing and packaging of her blood plasma a profitable undertaking, just as it is profitable for other entrepreneurs to purchase hen's eggs . . . for processing and distribution. . . . [W]e can find no reason to legally distinguish the sale of these raw products of nature from the sale of petitioner's blood plasma.

Id. at 1234. Here, Dolly sold and offered to sell his whole-blood samples to two universities and an infant's hospital. Analogous to *Green*, the marketability of Dolly's blood samples is predicated upon his rare genetic properties. Similarly, the sale of hen's eggs is not distinguishable from the sale of Dolly's blood samples. Therefore, Dolly's blood samples are deemed his property and thus protected from takings for public use without just compensation.

Property rights have also been found to exist in genetic material having the potentiality of life characteristic. See *Hecht v. Superior Court*, 16 Cal. App. 4th 836, 846, 20 Cal. Rptr. 2d 275, 281 (Ct. App. 1993). In *Hecht*, the petitioner sought to override a writ directing decedent's (petitioner's boyfriend) estate to destroy all of the decedent's sperm, which was in direct conflict with decedent's will. See *id.* at 844-45, 20 Cal. Rptr. 2d at 279-80. The court stated that "even if not governed by the general law of personal property, [the stored sperm] occupies 'an interim category that entitles them to special respect because of their potential for human life.'" *Id.* at 846, 20 Cal. Rptr. 2d at 281 (quoting *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992)). The court then held that, "at the time of his death, decedent had an interest, in the nature of ownership . . . sufficient to constitute 'property.'" *Id.* at 850, 20 Cal. Rptr. 2d at 283.

Analogous to *Hecht*, Dolly's blood samples have the potential for human life because they contain his genetic DNA, his entire genome. Current technology could potentially produce human life from Dolly's DNA through genetic engineering. Thus, similar to sperm, Dolly's interest in his blood samples is sufficient to constitute property and, thus, protected from takings for public use without just compensation.

Further legal support evincing the labeling of blood samples as property is derived from the Uniform Anatomical Gift Act ("UAGA"). See 8 U.L.A. 19 (1993). UAGA has been enacted in some form by all fifty states and authorizes the donation of body parts for transplant or medical research. See *id.* §§ 2-4, 6(a). UAGA thus implicitly categorizes body parts as property because the common usage of a donation is typically envisaged as the giving of "something." In this manner, Dolly has a property interest in his blood samples and is thus constitutionally protected to profit from productive use of those samples.

Opponents might argue that Dolly does not have property rights in his blood samples in light of *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990). However, this argument is erroneous because *Moore* is distinguishable both factually and legally. In addition, one might argue that the holding in *Moore* is anomalous in light of the current constitutional rights afforded to one's genetic material.

The plaintiff in the *Moore* case, Mr. Moore, was diagnosed with hairy-cell leukemia that necessitated the removal of his spleen. *See id.* at 125-26, 793 P.2d at 480-81, 271 Cal. Rptr. at 148. Mr. Moore consented to this treatment, and for the next seven years continued to give blood, sperm, and tissue samples with the understanding that these medical procedures were necessary to his health. *See id.* Unbeknownst to Mr. Moore, a doctor had managed to use Mr. Moore's spleen and other tissue to establish a cell line, which the doctor subsequently patented. *See id.* at 127, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49. Mr. Moore sued the doctor alleging, inter alia, claims for conversion and property rights in his excised cells and spleen. *See id.* at 128 & n.4, 793 P.2d at 482 & n.4, 271 Cal. Rptr. at 149 & n.4. The court held that Mr. Moore did not have sufficient property rights in his own cells to sustain a cause of action for conversion, and once the cells were removed from his body, they were considered abandoned. *See id.* at 136, 793 P.2d at 488, 271 Cal. Rptr. at 155.

The *Moore* court based its holding on the lack of sufficient arguments as well as on several policy considerations. *See id.* at 136-48, 793 P.2d at 488-97, 271 Cal. Rptr. at 155-64. The court noted that the complete lack of precedent in granting property rights to genetic material was paramount to its decision—"[o]nly property can be converted." *Id.* at 138, 793 P.2d at 490, 271 Cal. Rptr. at 157. Then, the court stated that the fact that a patent had been issued showed that the tissue in question was not the property of Mr. Moore; he could not possibly own what the PTO claimed another owned. *See id.* at 141-42, 793 P.2d at 492-93, 271 Cal. Rptr. at 159-60. Finally, the court addressed several policy considerations: the rights and interests of Mr. Moore were protected by the informed consent doctrine and to allow patients property interests in their cells would threaten to destroy the economic incentive necessary to conduct important research. *See id.* at 129-31, 140-42, 793 P.2d at 483-84, 491-93, 271 Cal. Rptr. at 150-51, 158-60. In a sense, the court applied a Kaldor-Hicks theory of economics and found that the economic and social benefits of cell research outweighed Mr. Moore's individual rights. *See Proprietary Rights and the Human Genome Project: A Legal and Economic Perspective*, 8 DIG. 45, 52 (2000).

The *Moore* case is distinguishable from the instant case in at least two respects. First, and foremost, Mr. Moore asserted a common law right to property, whereas here, Dolly is claiming constitutional rights to property under the Fifth Amendment. Secondly, Mr. Moore claimed property rights in genetic material that he had contractually “given” to research. In contrast, Dolly is claiming property rights in genetic material still in his “possession,” which he wants to sell/give to research. Accordingly, the holding in *Moore* is not applicable to the instant case.

In addition, the court’s analysis in *Moore* is both outdated and questionable if applied to the current state of the law. First, the court noted that the complete lack of precedent in granting property rights to genetic material was paramount to its decision. *See Moore*, 51 Cal. 3d at 136-37, 793 P.2d at 488-89, 271 Cal. Rptr. at 155-56. However, currently there is strong support for finding constitutionally protected rights to property in genetic material such as blood, sperm, and embryos. *See cases cited supra* Part IV.B.1. Second, the *Moore* court implicitly treated genetic material as “property” when it held that the genetic material in question was “abandoned” as well as when the court upheld the rationale of “informed consent” to transfer ownership of one’s genetic materials. Lastly, the court’s policy analysis overlooked many factors not accounted for, such as the chilling effect on patients consenting to research without the guarantees of their personal rights.

The government, in conferring NuGenEra with the right to exclude others’ use of claimed features of Dolly’s genome, has directly denied Dolly’s right to profit from the productive use of his blood samples. Moreover, Dolly has not been given just compensation for the denial of his property rights. Therefore, the patent issued to NuGenEra is unconstitutional and thus invalid.

2. Dolly’s privacy rights are violated by enforcement of the ‘271 patent because enforcement would deny Defendant Dolly his fundamental right to disconnect his body from the public domain

The constitutional right to privacy affords individuals personal autonomy over their bodies. *See Casey*, 505 U.S. at 857. The right to privacy preserves the right to create and maintain certain intimate and consensual relationships, free from governmental interference. Privacy rights also preserve the right to safeguard one’s body from

unwarranted governmental invasions or alterations. In the instant case, the government has denied Dolly's privacy rights in both of those characterizations.

a. Dolly has a right to disconnect his body from invasive apparatuses that keep him alive

The right to personal privacy was violated when a state law refused to allow the withdrawal of artificial food and hydration procedures from a person in a vegetative state. *See Cruzan*, 497 U.S. at 261-63. In *Cruzan*, the Court faced the question of whether the Constitution confers a "right to die." *Id.* at 277. The Court declared: "The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." *Id.* at 278. The Court went on to hold that "for purposes of this case, we assume that . . . a competent person [has] a constitutionally protected right to refuse lifesaving hydration and nutrition." *Id.* at 279 (emphasis added). Although the *Cruzan* Court stopped short of upholding a "right to die," subsequent cases interpret its holding to encompass a *fundamental right* to disconnect the body from the invasive apparatus keeping it alive. *See Vacco v. Quill*, 521 U.S. 793 (1997); *Washington v. Glucksberg*, 521 U.S. 702 (1997).

Here, Dolly is being "kept alive" by the "immortalized human cell line comprising his DNA" (Claim 3 of the '271 patent). The Government, in conferring upon NuGenEra the exclusive use of claimed features of Dolly's genome, denied Dolly his fundamental right to refuse this "lifesaving embodiment." Moreover, due to the disclosure requirements of patentability, Dolly's "life" has forever been preserved under the microscope of the public domain. Indeed, there is nothing more "invasive" than this patent (apparatus) "keeping him alive" for all eternity. Therefore, granting patent rights to Dolly's genome denies Dolly his *fundamental right* to disconnect his body from the invasive apparatus keeping it alive.

b. Dolly has a right to avoid genetic procreation

A law prohibiting the distribution of contraceptives to unmarried persons was deemed unconstitutional in *Eisenstadt*, 405 U.S. 438 (1972). The Court stated: "If the right of privacy means anything, it is the right of the *individual*, married or single, to be free from

unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.” *Id.* at 453 (emphasis in original). Recently, a law authorizing courts to order child visitation rights to “any person,” despite the parent’s objection, was deemed unconstitutional in *Troxel v. Granville*, 530 U.S. 57 (2000). The Court held that the statute infringed on one’s fundamental right to make decisions concerning the rearing of their offspring. *See id.* at 75.

Here, analogous to *Eisenstadt* and *Troxel*, Dolly’s fundamental right to make decisions regarding whether to bear, and how to rear his offspring, is impinged upon by the ‘271 patent. The patent grants NuGenEra exclusive rights over claimed features of Dolly’s genome. This provides NuGenEra with the power to create genetic “offspring” of Dolly through gestation and other genetic engineering procedures. Moreover, Dolly would have no control over the development of those offspring. Accordingly, Claim 1 and Claim 2 are invalid because they deny Defendant Dolly his fundamental privacy right to make decisions whether to bear or beget a child, as well as decisions on how to rear his offspring.

Opponents might argue that *Eisenstadt* and *Troxel* are distinguishable from the instant case because they deal with “traditional” notions of procreation and family as opposed to “procreation in a petri dish.” However, this distinction is without substance in light of cases that uphold one’s fundamental privacy interest in their excised genetic material.

For example, in *Hecht*, the genetic material at issue was a deceased man’s sperm that was stored in a sperm bank. The court held that a writ to destroy one’s sperm against his wishes was unconstitutional, concluding that one’s privacy rights require a donor’s intent to control the ultimate disposition of his sperm. *See Hecht*, 16 Cal. App. 4th at 846, 20 Cal. Rptr. 2d at 281. Sperm “occupies ‘an interim category that entitles them to special respect because of their potential for human life’” *Id.* (quoting *Davis*, 842 S.W.2d at 597).

Here, analogous to *Hecht*, Dolly’s genetic material is harbored by another. Similar to sperm, his genetic material deserves special respect because of its potential for human life. This special respect was denounced when the government issued patent rights in Dolly’s genome to another. Through the concept of patent licensing,

NuGenEra is allowed to exploit Dolly's "fundamental interest" in procreation as an item for negotiation and trade. The patent is unconstitutional because it denies Dolly's privacy right to "control the ultimate disposition" of one's genetic material that holds the "potential for human life."

A similar result was reached in *Davis*, where the court invoked the right of privacy in a dispute between a divorced couple over the fate of their frozen embryos. The dispute was over the disposition of cryogenically preserved embryos remaining from an in vitro fertilization process. *See Davis*, 842 S.W.2d at 589. The court held that "the right of procreation is a vital part of an individual's right to privacy." *Id.* at 600. The court then balanced the couple's conflicting interests and ruled that the husband's right to avoid genetic parenthood outweighed his former wife's right to procreate by donating the embryos to others for gestation. *See id.* at 604.

Analogous to *Davis*, Dolly's privacy interest over the disposition of his preserved genetic remains are in dispute. There is no need to balance the privacy interests of Dolly's genetic material between the parties because NuGenEra has no privacy rights with respect to Dolly's DNA. NuGenEra's governmentally protected ability to create "genetic offspring" directly conflicts with Dolly's right to avoid genetic parenthood. Thus, the '271 patent is unconstitutional because it denies Dolly his fundamental right to avoid procreation.

The government has denied Dolly's fundamental privacy rights by issuing the '271 patent to NuGenEra. The United States Constitution "forbids the government to infringe . . . 'fundamental' liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Glucksberg*, 521 U.S. at 721 (emphasis in original) (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)). Here, the issuance of the '271 patent does not serve a compelling governmental interest, and even if it did, surely there is a less burdensome alternative. Accordingly, the '271 patent is deemed unconstitutional and invalid.

V. CONCLUSION

Claim 1 and Claim 2 of the '271 patent are invalid for failure to meet statutory standards of patentability, namely, lack of utility, lack of enablement, and anticipation. They are also invalid for fundamental reasons of public policy—to grant exclusive rights to the use and sale of an individual's entire genome promotes commercial exploitation and exchange of a person's unique genetic identity. This is a particularly troubling negation of that individual's—Defendant Dolly's—right to bodily autonomy.

For the foregoing reasons, this Court should grant Defendant Dolly's Motion for Summary Judgment. To do otherwise would be an unconscionable transgression against Defendant Dolly's rights and the public good.

Dated: October 12, 2001

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